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Re-evaluation Note REV2012-07

Chloropicrin, Dazomet, Metam Sodium and Metam Potassium

Label Improvements for Antimicrobial Products

(publié aussi en français)

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

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Executive Summary

The purpose of this document is to notify registrants, pesticide regulatory officials, and the Canadian public of the re-evaluation status for the active ingredients chloropicrin, dazomet, metam sodium and metam potassium, and of label improvements for the antimicrobial products containing these active ingredients.

This Re-evaluation Note summarizes comments made to the PMRA in response to the Re-evaluation Note documents REV2010-10, *Soil Fumigants Proposed Mitigation Measures*, REV2010-12, *Chloropicrin – Proposed Mitigation Measures*, REV2010-13, *Dazomet – Proposed Mitigation Measures*, and REV2010-09, *Metam Sodium and Metam Potassium – Proposed Mitigation Measures*, published on 13 August 2010. This Re-evaluation Note also provides the PMRA's responses to the comments received.

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Background

Chloropicrin, dazomet, metam sodium and metam potassium are active ingredients under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). These four active ingredients are re-evaluated concurrently as part of a soil fumigant cluster. Soil fumigants are used to control soil pests or pathogens such as insects, nematodes, bacteria, fungi and weeds, which can disrupt plant growth and production. A fumigant is a volatile chemical that becomes a gas at relatively low temperatures (for example, chloropicrin), or a chemical that reacts to form a gas (for example, dazomet, metam sodium and metam potassium are converted to the active form, methyl isothiocyanate or MITC). In Canada, chloropicrin, dazomet, metam sodium and metam potassium are registered as pre-plant soil fumigants for use on a variety of terrestrial and/or greenhouse food/feed and non-food/non-feed crops, forests/woodlots, ornamentals, nurseries, seed beds and/or turf. The fumigants are applied and incorporated into the soil, sealed and then aerated prior to planting. These active ingredients are also registered as antimicrobials, either as remedial wood preservatives (for example, structural timber) or as preservatives in industrial process fluids (for example, pulp and paper mills, water cooling towers). All currently registered uses are considered in the re-evaluation.

The regulatory approach and proposed label improvements for the soil fumigant cluster were first presented in Re-Evaluation Note REV2010-10, *Soil Fumigants Proposed Mitigation Measures*, REV2010-12, *Chloropicrin – Proposed Mitigation Measures*, REV2010-13, *Dazomet – Proposed Mitigation Measures*, and REV2010-09, *Metam Sodium and Metam Potassium – Proposed Mitigation Measures*, published on 13 August 2010. This Re-evaluation Note describes this stage of PMRA's regulatory process for the re-evaluation of the antimicrobial products containing these active ingredients, as well as summarizes the Agency's decision and the reasons for it. The regulatory process for the re-evaluation of soil fumigant products containing chloropicrin, dazomet, metam sodium or metam potassium is communicated separately in Re-evaluation Note REV2012-08, *Chloropicrin, Dazomet, Metam Sodium and Metam Potassium Label Improvements for Soil Fumigant Products*. Comments pertaining to antimicrobial products received during the consultation process resulted in some changes to the proposed label improvements as described in the consultation documents. Appendix I summarizes the comments received during the consultation and provides the PMRA's response to these comments.

Regulatory Strategy

The PMRA's re-evaluation of the soil fumigant cluster is ongoing. At this time, the PMRA is requiring label improvements to further limit user exposure and further protect bystanders and the environment. These label improvements are considered a first step in the re-evaluation of the Canadian uses of the products containing these active ingredients.

Appendix II outlines the required label amendments for antimicrobial products containing chloropicrin. Appendix III outlines the label amendments required for antimicrobial products containing dazomet. Appendix IV outlines the label amendments required antimicrobial products containing metam sodium and metam potassium.

Additional Information

Any person may file a notice of objection[1] regarding this decision of label improvements for chloropicrin, dazomet, metam sodium and metam potassium within 60 days from the date of publication of this Re-evaluation Note. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) at www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd or contact the PMRA's Pest Management Information Service.

PMRA documents can be found on the Pesticides and Pest Management portion of Health Canada's website. PMRA documents are also available through the Pest Management Information Service.

[1] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Comments and Responses

1. Comments on the proposed label amendments

1.1 Basic hygiene label amendments

Some of the proposed basic hygiene label amendments to be added to the PRECAUTIONS section of label do not apply to products registered for antimicrobial uses in industrial settings. It is recommended that the PMRA separate the proposed requirements into soil fumigation and antimicrobial specific requirements for improved clarity.

Response

For improved clarity, the required label improvements for soil fumigant and antimicrobial products will be communicated in separate documents.

1.2 Air monitoring requirement

For metam sodium products used for the treatment of wooden poles and timber, the proposed air monitoring requirement before re-entering an area where a spill or leak has occurred will be challenging for users. Given the small package size (0.5-3.85 L), the size of a potential spill is limited. Furthermore, utility poles are treated in non-enclosed outdoor sites. On this basis, PMRA should specify a spill volume below which no air monitoring is necessary.

Response

Considering the small package size and that wood pools are treated outside, the requirement for air monitoring before re-entering an area where a spill or leak has occurred is no longer required.

Appendix II Label Amendments for Products Containing Chloropicrin

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products containing chloropicrin registered in Canada for antimicrobial uses must be revised to include the following amendments to further protect human health and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

> Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and a respirator during mixing, loading, transfer, application or any other handling activities. The respirator must be a NIOSH-approved full facepiece air-purifying respirator equipped with an organic (OV, NIOSH approval prefix TC-23C) cartridge and a particulate pre-filter (Type N, R, P, or HE, NIOSH approval number prefix TC-84A), or a gas mask with a canister approved for organic vapour (NIOSH approval number prefix TC-14G). The respiratory protection must fit properly, any obstruction to a proper fit should be removed (for example, beard, long sideburns).

II) The following statements must be included under **PRECAUTIONS** in a section entitled **Handler Use Precautions**:

> Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
>
> Remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing separately from other clothes before reuse.
>
> Store personal protective equipment out of reach of children and pets.
>
> Avoid touching 'clean' surfaces while wearing personal protective equipment (for example,, steering wheel, door handles, counter tops), or thoroughly clean these surfaces afterwards with water and detergent.
>
> Remove personal protective equipment immediately after handling this product. Remove personal protective equipment in a predetermined area separate from living or working areas.

Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Avoid touching eyes and face until you have washed your hands.

Never use the mouth to siphon product from containers or to blow out clogged lines, nozzles, etc.

Respirators should be stored in a sealed plastic bag until the next use, to preserve the life of the filter. Regularly change respirator cartridge filters.

Repair/replace torn or broken personal protective equipment.

Use hot water, heavy-duty liquid detergent, the highest water level setting, and the longest wash cycle. Keep and wash personal protective equipment separately from other laundry.

If heavily soiled, wash personal protective equipment two or three times. After washing, run the washing machine through a complete cycle with detergent. If possible, line-dry the clothing.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.

III) The following statements must be included in the **DIRECTIONS FOR USE** section:

For remedial treatment of wooden poles/timbers:

1. Plug the pre-drilled holes immediately after application;
2. Do not treat structures/beams indoors;
3. Do not drill an application hole through seasoning checks to apply product. If the hole intersects a check, plug the hole and drill another. If more than 2 treatment holes intersect an internal void or rot pocket, re-drill the holes farther up the pole into relatively solid wood.

DO NOT permit entry into spill or clean-up areas by unprotected persons until the air concentration of chloropicrin is measured to be less than 0.15 ppm.

DO NOT apply this product to wood that will be used in water.

Appendix III Label Amendments for Products Containing Dazomet

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products containing dazomet registered in Canada for antimicrobial uses must be revised to include the following amendments to further protect human health, and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

> *For the use in pulp and paper:*
> Wear coveralls over a long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, and protective eyewear during mixing, loading, application and all other handling activities.
>
> *For all other antimicrobial uses:*
> Wear a long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, and protective eyewear during mixing, loading, application and all other handling activities.

II) The following statements must be included under **PRECAUTIONS** in a section entitled **Handler Use Precautions**:

> *For liquid formulations (for example,, solutions, suspensions, emulsifiable concentrates):*
> Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
>
> Remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing separately from other clothes before reuse.
>
> Store personal protective equipment out of reach of children and pets.
>
> Avoid touching 'clean' surfaces while wearing personal protective equipment (for example: door handles, counter tops), or thoroughly clean these surfaces afterwards with water and detergent.
>
> Remove personal protective equipment immediately after handling this product. Remove personal protective equipment in a predetermined area separate from living or working areas.

Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Avoid touching eyes and face until you have washed your hands.

Never use the mouth to siphon product from containers or to blow out clogged lines, nozzles, etc.

Repair/replace torn or broken personal protective equipment.

Use hot water, heavy-duty liquid detergent, the highest water level setting, and the longest wash cycle. Keep and wash personal protective equipment separately from other laundry.

If heavily soiled, wash personal protective equipment two or three times. After washing, run the washing machine through a complete cycle with detergent. If possible, line-dry the clothing.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.

For solid formulations (for example,, granules, wettable/soluble powders):
Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide comes in contact with skin through spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing separately from other clothes before re-use.

Store personal protective equipment out of reach of children and pets.

Avoid touching 'clean' surfaces while wearing personal protective equipment (for example: door handles, counter tops), or thoroughly clean these surfaces afterwards with water and detergent.

Remove personal protective equipment immediately after handling this product. Remove personal protective equipment in a predetermined area separate from living or working areas.

Dust off any [granules *or* powder] from the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Avoid touching eyes and face until you have washed your hands.

Repair/replace torn or broken personal protective equipment.

Use hot water, heavy-duty liquid detergent, the highest water level setting, and the longest wash cycle. Keep and wash personal protective equipment separately from other laundry.

If heavily soiled, wash personal protective equipment two or three times. After washing, run the washing machine through a complete cycle with detergent. If possible, line-dry the clothing.

Discard clothing that has been heavily contaminated with this product. Do not reuse.

III) The following statements must be included under **DIRECTIONS FOR USE**:

For all products:
DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

Appendix IV Label Amendments for Products Containing Metam Sodium or Metam Potassium

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products containing metam sodium or metam potassium registered in Canada for antimicrobial uses must be revised to include the following amendments to further protect human health and the environment.

I) The following statements must be included in the **PRECAUTIONS** section:

For metam potassium products registered for use in cooling water towers:
Wear a long-sleeved shirt, long pants, shoes plus socks, chemical-resistant gloves, and eye protection during mixing, loading, application and all other handling activities.

For all other metam potassium products:
Wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves during mixing, loading, application or all other handling activities.

For metam sodium products registered for wood treatment uses:
Wear a long-sleeved shirt, long pants, shoes plus socks, and chemical-resistant gloves during mixing, loading, application or all other handling activities.

For metam sodium products registered for sewer uses:
Personal Protective Equipment:
Wear coveralls over a long-sleeve shirt and long pants, chemical-resistant gloves, chemical-resistant footwear plus socks, chemical-resistant apron (if transferring or loading the product or cleaning up spills or equipment), and a respirator during mixing, loading, transfer, application or any other handling activities. The respirator must be a NIOSH-approved half-face, full-face, or helmet/hood style respirator with either, an organic-vapour-removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G). In addition, wear face-sealing goggles if using a half-face respirator.

All support personnel who remain outside the treatment zone and who are not exposed to either liquid spray or vapours must wear a long-sleeved shirt, long pants, and shoes plus socks. In addition, when they may be exposed to liquid spray or vapours, they must have immediately available, and must wear in an emergency, the handler PPE listed above in this section.

Engineering Controls for Closed Loading and/or Transfer Systems:
Mixers and loaders must use a system capable of removing the pesticide from the shipping container and transferring it into tanks and/or application equipment. At any disconnect point, the system must be equipped with a dry disconnect or dry couple shut-off device that is warranted by the manufacturer to minimize drippage. Handlers must wear the personal protective equipment required in the **Personal Protective Equipment** section of this label.

Applicators must use an application nozzle designed to propel the application hose through the sewer using water-jetting capabilities. The nozzle should be designed to allow water to escape under pressure and thereby creating a rocket like effect that propels the nozzle forward while preparing the roots and the pipe for the application of herbicide. Once the hose and nozzle have arrived at the beginning of the application location the applicator will turn off the water pressure and the spring-loaded nozzle will switch to the foaming application.

The applicator must retrieve the hose hydraulically while applying foaming herbicide within the pipe.

A clean water rinse hose must be positioned to continuously rinse off the application hose as it is extracted from the pipe.

The applicator must shut off the foaming herbicide 15 meters before the applicator nozzle reaches the manhole in order to purge the last of the foaming herbicide from the hose prior to it exiting the manhole.

II) The following statements must be included under **PRECAUTIONS** in a section entitled **Handler Use Precautions**:

For all products:
Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Remove clothing immediately if pesticide comes in contact with skin through soaked clothing or spills. Then wash skin thoroughly and put on clean clothing. Wash contaminated clothing separately from other clothes before reuse.

Store personal protective equipment out of reach of children and pets.

Avoid touching 'clean' surfaces while wearing personal protective equipment (for example: steering wheel, door handles, counter tops), or thoroughly clean these surfaces afterwards with water and detergent.

Remove personal protective equipment immediately after handling this product. Remove personal protective equipment in a predetermined area separate from living or working areas.

Wash the outside of the gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Avoid touching eyes and face until you have washed your hands.

Never use the mouth to siphon product from containers or to blow out clogged lines, nozzles, etc.

Repair/replace torn or broken personal protective equipment.

Use hot water, heavy-duty liquid detergent, the highest water level setting, and the longest wash cycle. Keep and wash personal protective equipment separately from other laundry.

If heavily soiled, wash personal protective equipment two or three times. After washing, run the washing machine through a complete cycle with detergent. If possible, line-dry the clothing.

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product. Do not reuse them.

For metam sodium products registered for sewer uses:
Respirators should be stored in a sealed plastic bag until the next use, to preserve the life of the filter. Regularly change respirator cartridge filters.

III) The following statements must be included in the **DIRECTIONS FOR USE** section:

For all products registered for use in cooling water towers, pulp and paper and petroleum industries:
DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

For products registered for wood treatment uses:
For remedial treatment of wooden poles/timbers:

1. Plug the pre-drilled holes immediately after applications;
2. Do not treat structures/beams indoors;
3. Do not drill an application hole through seasoning checks to apply product. If the hole intersects a check, plug the hole and drill another. If more than 2 treatment holes intersect an internal void or rot pocket, re-drill the holes farther up the pole into relatively solid wood.

DO NOT apply this product to wood that will be used in water.

For metam potassium products registered for use in cooling water towers:
A metering pump system must be used when applying this product.

For metam sodium products registered for sewer uses:
Applicators must notify downstream waste water treatment facilities prior to start of Metam sodium applications so that they may monitor the operations of the wastewater treatment plant.

IV) The following statements must be included in the **ENVIRONMENTAL HAZARD** section:

For all products:
Toxic to aquatic organisms.